Institutional Review Board

North Dakota Department of Human Services
Application for IRB Review of Research
Involving the Use of Human Subjects

Type all answers

1. General Personnel Information

Principal Investigator (Student if Applicable): _____

☐ Non-DHS ☐ DHS Division: _____ Tel#: _____
Fax#: _____
Address: (Home or College): _____ E-mail: _____
_____

Co-Principal Investigator (Faculty advisor if applicable): _____

☐ Non-DHS ☐ DHS Division: _____ Tel#: _____
Fax#: _____
E-mail: _____
Address: _____

2. Protocol General Information

Title: _____
Title on informed consent (If different from project title): _____
Total project period approval being sought is: From: _____ To: _____
Number of subjects or number of Records / Charts to be reviewed: _____

Male ☐ Female ☐ Age Range: _____

Funding source: _____
Multi-center study? ☐ Yes Number of CTRS: _____ ☐ No

Has your project been (or will it be) submitted to another IRB for review?

☐ Yes ☐ No If yes, please complete the following:

Name of IRB	Date Submitted	Status
_____	_____	☐ Approved ☐ Disapproved ☐ Pending
_____	_____	☐ Approved ☐ Disapproved ☐ Pending
_____	_____	☐ Approved ☐ Disapproved ☐ Pending

Proposal #_____

3. Institutions and/or Facilities Used in this Research

☐ WCHSC	☐ SCHSC	☐ Database (specify):
☐ LRHSC	☐ NCHSC	
☐ BHSC	☐ NWHSC	
☐ SEHSC	☐ State Hospital	☐ Other:
☐ NEHSC	☐ NDDC	

Note: If an institution name is followed by an asterisk (*), or it is not among those listed, you must include an approval letter from that institution with your application.

4. Special or Vulnerable Study Subjects Involved in this Research: ☐ **NA**

(Attach the appropriate informed consent document for each subject population checked below.)

☐ Pregnant Women ☐ Children (<18) ☐ Embryos/fetuses ☐ Juvenile offenders ☐ Prisoners

☐ Persons with acute and/or severe mental/physical disabilities ☐ Elderly persons ≥ 65

☐ Non-English speaking persons-identify language: _____ (Attach translated consent.)

5. Protocol Design and Subject Specifications

- State the hypothesis to be tested or the purpose of the proposed research; and provide the relevant background pertinent to the hypothesis or purpose of the study including the rationale for the experimental procedure. ***(Limit your answer to 150 words or less) (Tab down.)***

- Describe the source and selection method of the experimental and control subjects. If you are advertising for research subjects, attach a copy of your advertisement for review. ***(Tab down.)***

- Describe the inclusion/exclusion criteria for the subjects you will use in the study. ***(Tab down.)***

- Describe the type of research design, materials, methods, data collection and analysis; and, how much time is needed for participation.
  Note: Be sure to include copies of any scales, questionnaires, etc. that you will use in the study.
  (Tab down)

- Describe your consent process and how you will insure confidentiality of the subjects. ******
  (Tab down.)

- List any cost/financial remuneration to subjects as a result of participating in this research. ***(Tab down.)***

- Describe the anticipated benefits to the subjects in this research. ***(Tab down.)***

- Describe the risks and/or side effects (physical, psychological, and/or social) to the subjects in this research. Please list any precautions you are taking to minimize these risks. ***(Tab down.)***

****** **Note:** In some circumstances investigators can **request** waiver of documentation of Informed Consent (signature requirement) or waiver of Informed Consent. Please be aware that such requests should be made only if there are compelling reasons to do so.

Proposal #_____

6. Principal Investigator Statement of Assurance

The proposed investigation involves the use of human subjects. I am submitting this form with a description of my project prepared in accordance with the North Dakota Department of Human Services' IRB policies and its affiliates' policies for the protection of human subjects participating in research. I certify that I have either read "The Belmont Report" or viewed the IRB instructional videotapes. I understand the Department's policies concerning research involving human subjects and agree to:

a. obtain voluntary and knowing informed consent of subjects capable of providing consent who are requested to participate in this project;
b. assure that before human subjects are involved in this project, proper consideration will be given to:
    1. the risks to the subjects
    2. the anticipated benefits to the subjects and others
    3. the importance of the knowledge that may be reasonably expected to result
    4. the need for additional safeguards if the human subjects are especially vulnerable;
c. report to the IRB any unanticipated adverse effects on subjects which become apparent during the course or as a result of experimentation and the actions taken as a result (Off-site Adverse Event Report or On-site Adverse Event Report);
d. cooperate with the IRB with the continuing review of this project (Research Progress Report);
e. obtain prior approval from the IRB before amending or altering the scope of the project or implementing changes in approved consent form (Change in Procedure or Principal Investigator Application);
f. maintain documentation of consent forms and progress reports as required by institutional and Federal policies;
g. accept the responsibility for the conduct of this research and the supervision of associated personnel **(i.e., research or graduate assistants and/or co-investigators. These individuals must sign the confidentiality statement at the end of this application. I understand that these statements must be kept on file by the PI.)** and human subjects as required by law;
h. provide a report of the results of the study to the IRB (Research Progress Report);
i. allow the North Dakota Department of Human Services to utilize and disseminate the data I gather and analyze;
j. in the event I am requested to share the data generated by this study at a later time by a *bona fide* researcher, I shall release only data that has either had identifying items deleted or has been encrypted so as to prevent the connection of identity with data.

Signature of Principal Investigator (Signature of Student, if applicable)	Date
Co-Principal Investigator (Faculty advisor, if applicable)	Date

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7. Signature Requirements

Approval of Division Director

Signature of Director	Title	Department	Date

Director's Name (Typed or Printed)	Date

Proposal #_____

IRB Proposal #_____

FOR IRB USE ONLY:

_____ Full Board Review

_____ Exempt

_____ Expedited Category #

Expedited Review By:

_____

_____

_____

_____ _____

IRB Chairperson Signature Date

Proposal #_____

IMPORTANT!

In order to have your protocol reviewed you must include the following:

1.
One copy of the grant application (if the study is federally funded), or the research protocol, thesis outline or project description. (Please note: This must include the title of your study as referenced on your IRB application);

2.
One copy of all questionnaires, scales, etc. to be used in the study;

3.
One copy of the informed consent form(s) for adults, children, or both, as applicable, along with one copy of any necessary informed consent form translation;

4.
The original IRB application with original signatures, with any advertisements, affiliate approval letters, etc.

(Please Note: If any of the above items are not submitted with your application – this will delay the process. Final approval of the study is contingent on receipt of these items.)

Please return this application and the relevant attachments to:

Mental Health and Substance Abuse Services
Attn: DHS IRB Chair
1237 West Divide Ave, STE. 1C
Bismarck, ND 58501-1208

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NOT TO BE SUBMITTED WITH THE IRB APPLICATION

TO BE KEPT ON FILE BY THE PRINCIPAL INVESTIGATOR

Confidentiality Statement
North Dakota Department of Human Services

NOTICE CONCERNING CONFIDENTIALITY OF INFORMATION PERTAINING TO PARTICIPANTS IN DHS RESEARCH

Please note: to be signed by Co-Investigators, Research/Graduate Assistants, and all other individuals who would have access to confidential information covered by the IRB approved project. This form should be kept on file by the Principal Investigator until the final report on the project has been accepted by the IRB. Representatives of the IRB may ask to see copies of this for personnel associated with this project.

All information pertaining to individuals participating as research subjects in DHS research projects, including but not limited to names, addresses, and other identifying information, must be held in strictest confidence. Unauthorized disclosure of information related to research participants by staff constitutes serious misconduct, which is subject to disciplinary action up to and including termination. Under certain circumstances, unauthorized disclosure could result in criminal, civil, or judicial penalty. Disclosure of confidential information must adhere to procedures contained in DHS Institutional Review Board (IRB) approved Informed Consent documents to participate in research as approved by the IRB. This does not prevent disclosures required or permitted by state or federal law for the protection of human life or protection of minor children.

Acknowledgement

This will acknowledge that I have read and understand the above notice and that I have been given a copy.

Signatures of all other Authorized Research Investigators:

_____
Signature of Principal Investigator

_____
Date

_____
Witness

_____ _____
Print or Type Name Signature

_____
Date

_____ _____
Print or Type Name Signature

_____
Date

_____ _____

Proposal #_____

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